

**TAB B**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:

Greg Swords

Serial No. 10/517,843

Filed: July 12, 2005

For: Craniofacial Implant

Art Unit: 3774

Examiner: Suba Ganesan

Attorney Docket No.: 37370/339252

**DECLARATION OF** Don O. Kikkawa, MD

1. My name is Don Kikkawa I am over the age of 21, and I am competent to make this declaration based upon my personal knowledge.
2. I am a surgeon who uses the TITAN™ implant, which I understand is the product made according to the above-referenced application.
3. The TITAN™ implant is a porous polyethylene matrix having a metal mesh embedded therein. In some versions of the implant, there is a barrier coating on one or both sides. The TITAN™ implant provides clear and distinct benefits over other craniofacial implants previously on the market.
4. First, porous polyethylene implants for orbital reconstruction *without* a surgical grade metal mesh do not always meet my needs because they do not provide adequate strength needed for certain surgeries, they are not always malleable, they have less shape memory than metal mesh alone, and they are not readily visualized on postoperative radiographs or CT scans. Second, metal mesh alone (not contained within a sheet of thermoplastic resin)

does not always meet my needs because it does not allow for cellular ingrowth, it does not provide a smooth solid barrier surface, which is sometimes needed to completely prevent passage of fluids and other biological matter, and it can be difficult to insert through small incisions because of its sharp or irregular edges.

5. When the TITAN™ implant was introduced, it was the first product on the market to combine porous polyethylene and titanium mesh into one implant by embedding the mesh within polyethylene, obtaining the benefits of both materials.


6. Upon its introduction, I was (and I continue to be) quite pleased with the features that the TITAN™ implant provides. It combines strength and flexibility, so that I can bend the implant and it maintains its shape. It also provides different options – implants that allow fibrovascular ingrowth on both sides (porous/porous), fibrovascular ingrowth on only one side (porous/barrier), or preventing ingrowth completely (barrier/barrier). I currently use the TITAN™ implant in most of my large or complex orbital reconstruction surgeries.

7. My decision to use (and continue to use) the TITAN™ implant is not influenced by cost, advertising, my relationship with Porex, nor any other economic or commercial factors. I choose to use TITAN™ implants because the features they provide are highly superior to any other product on the market. The combination of porous polyethylene with a surgical grade metal mesh embedded therein is why I (and many of my colleagues) continue to purchase and use the TITAN™ implant.

8. As the person signing below, I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false

statements and the like so made are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code.

Dated: 8/27/08

  
Name: Don Kikawa, MD

Citizenship: USA

Post Office Address: \_\_\_\_\_

9415 Campus Point Drive

La Jolla, CA 92093-0946



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**Don Kikkawa, M.D.**

*Ophthalmology (Oculoplastic Surgery)*

**REQUEST AN APPOINTMENT WITH THIS DOCTOR**

Dr. Kikkawa serves as Division Chief of Ophthalmic Plastic and Reconstructive Surgery. This specialty combines traditional studies and patient care as an ophthalmologist with a fellowship in reconstruction and plastic surgery around the eyes. The extensive training uniquely qualifies these specialists to perform delicate surgery on the eyelids, around the eyes, the drainage system, and on the bones around of the eye. Dr. Kikkawa finds the field very gratifying; reversing the effects of aging, restoring a normal appearance to disfigured trauma or diseased patients, and eliminating vision-threatening tumors.

Respected for his knowledge and surgical experience, patients travel to San Diego from throughout the United States, as well as other countries, for Dr. Kikkawa's skills. He has hosted several highly praised medical conferences for his colleagues and selected by them to Best Doctors in America. Additionally, Dr. Kikkawa serves as one of three Shiley specialists that comprise our unique Thyroid Eye Clinic to treat patients with this disfiguring and vision threatening disease.

**Board Certification:** Ophthalmology

**Experience:** Dr. Kikkawa is Chief of Ophthalmic Plastic and Reconstructive Surgery at UCSD Healthcare's Shiley Eye Center.

**Education:** St. Louis University School of Medicine  
St. Louis, Missouri  
Doctor of Medicine

**Training:** Residency in Ophthalmology  
Jules Stein Eye Institute  
University of California  
Los Angeles, California

**Hospital Affiliations:** UCSD Thornton Hospital, La Jolla  
UCSD Medical Center, Hillcrest

**Office Address:** Shiley Eye Center

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